

REMARKS

Claims 2 and 4-8 are pending. Claims 2 and 4-6 are amended and new claims 7 and 8 are added. Support for the amendments can be found in the specification and in the claims as originally filed. In particular, support for the amendments to claims 2 and 4 may be found on page 7, line 11 of the specification and support for the amendments to claims 5 and 6 can be found on page 4 of the specification, lines 6-10. No new matter is added.

The Office Action rejects claims 5 and 6 under 35 U.S.C. § 112, first paragraph, for containing new matter. Applicants respectfully submit that this rejection is overcome in view of the amendments to claims 5 and 6, which corrected the typographical error of "500" to "400," as supported at page 4, lines 6-10 of the specification. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 5 and 6 under 35 U.S.C. § 112, first paragraph.

The Office Action rejects claims 2 and 4-6 under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicants respectfully submit that this rejection is also overcome in view of the amendments to claims 2 and 4, as applicants no longer recite "11" genotype or "12" genotype. Applicants again note that these amendments are supported by the specification at Example 1, page 7, middle paragraph, disclosing a method for identifying this variant and especially the sequence within the disclosure.

Thus, Applicants respectfully request that the rejection under 35 U.S.C. 112, second paragraph be reconsidered and withdrawn.

The Office Action rejects claims 2 and 4-6 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Office Action asserts that the "11" and "12"

genotypes are clearly undefined. Further, the Office Action asserts that even if these genotypes were clearly defined, that the specification is not enabling as there is no predictability between polymorphisms and their association with a phenotypic trait (citing Hacker et al., "Lack of association between an interleukin-1 receptor antagonist gene polymorphism and ulcerative colitis," *Gut*, (1997) Vol. 40, pp. 623-627) and that the efficacy of the shorter duration of claims 5 and 6 is unsupported as from specification only seems to support a duration of 9 months (See Specification, Example 1).

Applicants respectfully submit that the indefiniteness rejections as to the "11" and "12" are overcome in view of the amendments to claims 2 and 4. Please see the above arguments.

Applicants also respectfully disagree with statement in the Office Action that Hacker et al. was "unable to confirm an association between a gene polymorphism and ulcerative colitis" (Office Action, page 5, lines 12-13). Applicants respectfully submit that Hacker et al. does not teach or suggest unpredictability between a polymorphism and a phenotype.

Hacker et al. concluded that there was "[N]o association of a polymorphism in the interleukin-1 receptor antagonist gene with ulcerative colitis in a southern German population" (Hacker et al., page 623, left column, "conclusions" section). Hacker et al. also states that "[I]t seems unlikely that allele 2 of this polymorphism represents a marker for ulcerative colitis in the general population" (Hacker et al., page 626, left column, last paragraph). Further, the title of the article itself states "Lack of association..." Thus, Applicants respectfully submit that Hacker et al. does not teach or suggest any unpredictability between polymorphisms and phenotypes, but instead

confirms a lack of relationship between the specific polymorphism and phenotype under study in that article.

Applicants respectfully submit that the present specification supports the exercise period of amended claims 2 and 4-6. The specification specifically states that the exercise period may be from "about 50-400 days, preferably from 70-350 days or 100-300 days" (Specification, page 4, lines 8-10).

Thus, Applicants respectfully request that the rejections under 35 U.S.C. 112, first paragraph, be reconsidered and withdrawn.

In view of the remarks above, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon.

In the event this paper is not considered to be timely filed, Applicants hereby petition for an appropriate extension of time. The fee for this extension may be charged to our Deposit Account No. 01-2300. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 01-2300, referencing attorney docket no. 108172-00071.

Respectfully submitted,



Amy E. L. Schoenhard
Registration No. 46,512

Customer No. **004372**
ARENT FOX PLLC
1050 Connecticut Avenue, N.W., Suite 400
Washington, D.C. 20036-5339
Tel: (202) 857-6000
Fax: (202) 638-4810
Enclosure: Petition for Extension of Time